



Please type a plus sign (+) inside this box → ☒

Approved for use through 10/31/2002. PTO/SB/21 (08-00)  
OMB 0861-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/054,498
Filing Date	January 22, 2002
First Named Inventor	John Welsh
Group Art Unit	1642
Examiner Name	Hayshemi
Attorney Docket Number	P0026US20

Total Number of Pages in This Submission

7 + \*\*

### ENCLOSURES (check all that apply)

- |  |   |  |
|--|---|--|
| <input type="checkbox"/> Fee Transmittal Form<br><br><input type="checkbox"/> Fee Attached<br><br><input type="checkbox"/> Amendment / Response<br><br><input type="checkbox"/> After Final<br><br><input type="checkbox"/> Affidavits/declaration(s)<br><br><input type="checkbox"/> Extension of Time Request<br><br><input type="checkbox"/> Express Abandonment Request<br><br><input checked="" type="checkbox"/> Information Disclosure Statement<br><br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><br><input type="checkbox"/> Response to Missing Parts/ Incomplete Application<br><br><input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Assignment Papers (for an Application)<br><br><input type="checkbox"/> Drawing(s)<br><br><input type="checkbox"/> Licensing-related Papers<br><br><input type="checkbox"/> Petition<br><br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><br><input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address<br><br><input type="checkbox"/> Terminal Disclaimer<br><br><input type="checkbox"/> Request for Refund<br><br><input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance Communication to Group<br><br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><br><input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)<br><br><input type="checkbox"/> Proprietary Information<br><br><input type="checkbox"/> Status Letter<br><br><input type="checkbox"/> Other Enclosure(s) (please identify below):<br><br><b>** Copies of 38 references; Return postcard</b> |
|--|---|--|

Remarks

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name  
Hugh Wang, Reg. No. 47,163

Signature

Date

November 13, 2002

### CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: US Patent and Trademark Office, PO Box 2327, Arlington VA 22202 on this date: November 13, 2002

Typed or printed name  
Hugh Wang

Signature

Date

November 13, 2002

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

RECEIVED  
NOV 19 2002  
TECH CENTER 1800 2900



I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: US Patent and Trademark Office, PO Box 2327, Arlington VA 22202 on this date November 13, 2002

By: \_\_\_\_\_

Hugh Wang

PATENT  
Attorney Docket No.: P0026US20

TECH CENTER 1600/2900

NOV 19 2002

RECEIVED

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

John Welsh et al.

Application No.: 10/054,498

Filed: January 22, 2002

For: Genes Overexpressed In Prostate Disorders As Diagnostic And Therapeutic Targets

Examiner: Hayssemi

Art Unit: 1642

Information Disclosure Statement

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The references cited on attached form PTO/SB/08A are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" section on any patents to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement, and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicants believe that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No.:

50-1885. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Hugh Wang', with a stylized, sweeping flourish extending to the right.

Hugh Wang  
Reg. No. 47,163

Genomics Institute of the Novartis Research Foundation  
10675 John Jay Hopkins Drive  
San Diego, CA 92121  
Tel: (858) 812-1500  
Fax: (858) 812-1981

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

1

of

4

**Complete if Known**

Application Number	10/054,498
Filing Date	January 22, 2002
First Named Inventor	John Welsh
Group Art Unit	1642
Examiner Name	Hayshemi
Attorney Docket Number	P0026US20

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	AA	WO 01/34802 A2	May 17, 2001	Corxia Corp.		

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AB	BOOTCOV et al., Proc. Natl. Acad. Sci. USA, Vol. 94, No. 21, pp. 11514-11519 (1997); MIC-1, a novel macrophage inhibitory cytokine, is a divergent member of the TGF- superfamily.	
	AC	BRAWER, Semin. Surg. Oncol. 18: 3-9, 2000; Prostate-specific antigen.	
	AD	BRAWER et al., Am. J. Clin. Pathol. 92: 760-764, 1989; Serum prostate-specific antigen and prostate pathology in men having simple prostatectomy.	
	AE	BUSSEMAKERS et al., Cancer Res., Vol. 59, pp. 5975-5979 (1999); DD3: a new prostate-specific gene, highly overexpressed in prostate cancer.	
	AF	CATALONA et al., JAMA 270:948-954, 1993; Detection of organ-confined prostate cancer is increased through prostate-specific antigen-based screening.	
	AG	CHANG et al., Cancer Res., Vol. 57, pp. 4075-4081 (1997); Differentially expressed genes in androgen-dependent and -independent prostate carcinomas.	

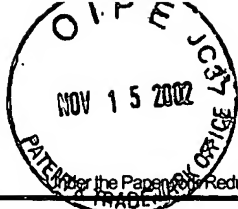
Examiner  
SignatureDate  
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

RECEIVED  
NOV 19 2002



Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 4

### Complete if Known

Application Number	10/054,498
Filing Date	January 22, 2002
First Named Inventor	John Welsh
Group Art Unit	1642
Examiner Name	Hayshemi
Attorney Docket Number	P0026US20

TECH CENTER 1642/2900

NOV 19 2002

RECEIVED

### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AH	CHOO et al., Prostate, Vol. 40, pp. 150-158 (1999); Immortalization of human prostate epithelial cells by HPV 16 E6/E7 open reading frames.	
	AI	DHANASEKARAN et al., Nature 412: 822-826 (2001); Delineation of prognostic biomarkers in prostate cancer.	
	AJ	EMMERT-BUCK et al., Am. J. Pathol., Vol. 156, pp. 1109-1115 (2000); Molecular Profiling of Clinical Tissue Specimens: Feasibility and Applications	
	AK	FERDINANDUSSE et al., J Lipid Res 2000 Nov;41(11):1890-6; Subcellular localization and physiological role of alpha-methylacyl-CoA racemase.	
	AL	HOANG et al., Am. J. Pathol., Vol. 156, pp. 857-864 (2000); A novel association between the human heat shock transcription factor 1 (HSF1) and prostate adenocarcinoma.	
	AM	HROMOS et al., Biochim. Biophys. Acta. Vol. 1354, No. 1, pp. 40-44 (1997); PLAB, a novel placental bone morphogenetic protein.	
	AN	HUANG et al., Genomics, Vol. 59, pp. 178-186 (1999); Prostate Cancer Expression Profiling by cDNA Sequencing Analysis.	
	AO	JIANG et al., Am. J. Surg. Pathol. 25: 1397-1404, 2001; P504S: a new molecular marker for the detection of prostate carcinoma.	
	AP	KANNAN et al., FEBS Lett., Vol. 470, No. 1, pp. 77-82 (2000); Profile of gene expression regulated by induced p53: connection to the TGF- family.	
	AQ	KAZAMA, J. Biol. Chem., Vol. 270, pp. 66-72 (1995); Hepsin, a Putative Membrane-associated Serine Protease, Activates Human Factor VII and Initiates a Pathway of Blood Coagulation on the Cell Surface Leading to Thrombin Formation.	
	AR	KUHAJDA, in Nutrition, Vol. 16, No. 3, pp. 202-208 (2000); Fatty-acid synthase and human cancer: new perspectives on its role in tumor biology.	
	AS	LALANI et al., Cancer Metastasis Rev., Vol. 16, pp. 29-66 (1997); Molecular and cellular biology of prostate cancer.	

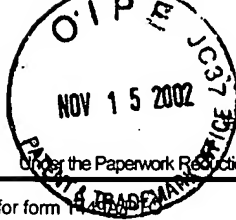
Examiner  
Signature

Date  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form PTO/SB/08B(10-01)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 4

**Complete if Known**

Application Number	10/054,498
Filing Date	January 22, 2002
First Named Inventor	John Welsh
Group Art Unit	1642
Examiner Name	Hayshemi
Attorney Docket Number	P0026US20

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AT	LI et al., Science, Vol. 275, pp. 1943-1947 (1997); PTEN, a Putative Protein Tyrosine Phosphatase Gene Mutated in Human Brain, Breast, and Prostate Cancer	
	AU	LUO et al., Cancer Res. 61: 4683-88, 2001; Human prostate cancer and benign prostatic hyperplasia: molecular dissection by gene expression profiling.	
	AV	MAGEE et al., Cancer Res. 61: 5692-96, 2001; Expression profiling reveals hepsin overexpression in prostate cancer.	
	AW	MARCELLI et al., Cancer Res., Vol. 60, pp. 944-949 (2000); Androgen receptor mutations in prostate cancer.	
	AX	MIKI et al., PNAS 98: 2199-2204, 2001; Delineating developmental and metabolic pathways in vivo by expression profiling using the RIKEN set of 18,816 full-length enriched mouse cDNA arrays.	
	AY	NAM et al., J. Clin. Oncol. 18: 1036-1042, 2000; Serum human glandular kallikrein-2 protease levels predict the presence of prostate cancer among men with elevated prostate-specific antigen.	
	AZ	PILARSKY et al., Prostate, Vol. 36, pp. 85-91 (1998); Expression of the extracellular matrix signaling molecule Cyr61 is downregulated in prostate cancer.	
	BA	PIZER et al., Prostate 2001 May 1;47(2):102-10; Increased fatty acid synthase as a therapeutic target in androgen-independent prostate cancer progression.	
	BB	SUN et al., Cancer Res., Vol. 57, pp. 18-23 (1997); Human prostatic carcinoma oncogene PTI-1 is expressed in human tumor cell lines and prostate carcinoma patient blood samples.	
	BC	SCHER et al., Urology 55: 323-327, 2000; Clinical states in prostate cancer: toward a dynamic model of disease progression.	
	BD	SAFFRAN et al., Cancer Metastasis Rev. 18: 437-449 (1999); Target antigens for prostate cancer immunotherapy.	

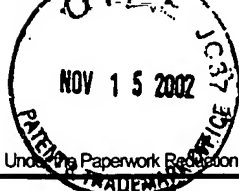
Examiner  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

RECEIVED  
NOV 19 2002



PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 4 of 4

**Complete if Known**

Application Number	10/054,498
Filing Date	January 22, 2002
First Named Inventor	John Welsh
Group Art Unit	1642
Examiner Name	Hayshemi
Attorney Docket Number	P0026US20

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issu number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BE	STAMEY et al., J. Urol. 166: 2171-77, 2001; Molecular genetic profiling of Gleason grade 4/5 prostate cancers compared to benign prostatic hyperplasia.	
	BF	TANIMOTO et al., Cancer Res., Vol. 57, pp. 2884-2887 (1997); Hepsin, a cell surface serine protease identified in hepatoma cells, is overexpressed in ovarian cancer.	
	BG	TORRES-ROSADO et al., Proc. Natl. Acad. Sci. USA, Vol. 90, pp. 7181-7185 (1993); Hepsin, a Putative Cell-Surface Serine Protease, is Required for Mammalian Cell Growth.	
	BH	TSUJI et al., J. Biol. Chem., Vol. 266, pp. 16948-16953 (1991); Hepsin, a cell membrane-associated protease. Characterization, tissue distribution, and gene localization.	
	BI	VOELLER et al., Cancer Res., Vol. 58, pp. 2520-2523 (1998); Beta-catenin mutations in human prostate cancer.	
	BJ	VU et al., J. Biol. Chem., Vol. 272, pp. 31315-31320 (1997); Identification and Cloning of the Membrane-associated Serine Protease, Hepsin, from Mouse Preimplantation Embryos.	
	BK	WU et al., J. Clin. Invest., Vol. 101, pp. 321-326 (1998); Generation and characterization of mice deficient in hepsin, a hepatic transmembrane serine protease.	
	BL	YANG et al., Cancer Res., Vol. 58, pp. 3732-3735 (1998); Identification of genes expressed differentially by LNCaP or PC-3 prostate cancer cell lines.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.